

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 09-037 (RBK)(JS)
	)	CONSOLIDATED
LUPIN LTD., et al.,	)	
	)	
Defendants.	)	
	)	
_____	)	
	)	
SHIONOGI PHARMA, INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 10-135 (RBK)(JS)
	)	
MYLAN, INC., et al.,	)	
	)	
Defendants.	)	

**PLAINTIFF SHIONOGI INC.'S OPPOSITION TO  
LUPIN'S MOTION TO STAY OR MODIFY ENFORCEMENT  
OF THE COURT'S PRELIMINARY INJUNCTION ORDER**

OF COUNSEL:

David A. Manspeizer  
David B. Bassett  
Peter Shen  
Christopher Noyes  
WILMER CUTLER PICKERING HALE  
AND DORR LLP  
399 Park Avenue  
New York, NY 10022  
(212) 230-8800

MORRIS, NICHOLS, ARSHT & TUNNELL LLP  
Jack B. Blumenfeld (#1014)  
Karen Jacobs Loudon (#2881)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899-1347  
(302) 658-9200  
jblumenfeld@mnat.com  
kloudon@mnat.com

*Attorneys for Plaintiff Shionogi, Inc.*

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## **I. NATURE AND STAGE OF PROCEEDINGS**

After extensive briefing and a lengthy hearing, this Court granted Shionogi's motion for preliminary injunction on December 6, 2011 (D.I. 279 and 280.) As required by the Court, Shionogi posted a bond of \$15M on December 12, 2011. (D.I. 287.) On December 14, 2011, Lupin filed a motion to stay or modify the Court's Order. (D.I. 288.) Shionogi now responds to and opposes Lupin's motion for the reasons set forth below.

## **II. SUMMARY OF ARGUMENT AND STATEMENT OF FACTS**

Lupin's motion to stay or modify enforcement of the Court's December 6, 2011 Order granting Shionogi's motion for preliminary injunction ("Order") should be denied for at least three reasons.

**First**, Lupin's motion is not, as it asserts, designed to "restore the balance among the parties" and "preserve the status quo." (D.I. 289 at 1, 5.) To the contrary, Lupin's motion, brought under the guise of Rule 62, simply seeks reconsideration of the Order so that Lupin can continue selling its generic copy of FORTAMET® before this Court has an opportunity to make a final determination on the merits of Shionogi's claims—claims that the Court found are likely to succeed at trial. (D.I. 279 at 11.) Indeed, Lupin's requested relief would permit the very conduct the Court enjoined, by allowing Lupin to flood the market with additional, infringing product. Lupin admits as much, stating that the "status quo" it seeks will allow Lupin to "make new sales of [its] generic metformin product[]." (D.I. 289 at 5.) Staying the Court's Order and allowing Lupin to sell its generic product during its appeal or until trial in this matter (anticipated to be held within a year) will have an additional devastating impact on Shionogi—resulting in precisely the irreparable harm the injunction is designed to avoid. (*See* D.I. 279 at 18.) Lupin presents no new facts, law, or arguments that would justify this extraordinary relief.

**Second**, Lupin cannot satisfy its “very heavy burden of persuasion” under Rule 62. *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, 2009 U.S. Dist. LEXIS 56453, at \*7 (D.N.J. 2009). Lupin’s motion presents no new facts or law that would justify a stay of the Order—it simply recites the same facts, the same law, and the same arguments already extensively briefed and argued to the Court during the preliminary injunction proceedings—facts, law and arguments the Court has already (correctly) found not persuasive. Rehashing the same infringement positions, Lupin again disavows its FDA-approved label and contradicts both the Court’s claim construction Order and positions Lupin took during claim construction proceedings. Lupin similarly regurgitates its validity arguments, making the same prosecution history argument addressed and rejected by the Court in ruling on the injunction motion. On harm, Lupin again fails to acknowledge that any alleged harm it has or may suffer was both reasonably foreseeable and self-inflicted. This includes, in particular, its decision to launch at-risk and start the clock on its 180-day exclusivity. In short, Lupin’s motion does nothing more than restate and repeat the same arguments previously considered and rejected by the Court. This is not sufficient under Rule 62. *See Sanofi-Aventis*, 2009 U.S. Dist. LEXIS 56453, at \*6-7 (denying Rule 62 motion).

**Finally**, Lupin’s motion fails because it does not and cannot demonstrate that it is likely to succeed on appeal to the Federal Circuit. Although it never recites the applicable standard, Lupin can only succeed on appeal by demonstrating that this Court abused its discretion by making “a clear error of judgment in weighing the relevant factors or bas[ing] its exercise of discretion on an error of law or on clearly erroneous factual findings.” *Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1200 (Fed. Cir. 2007) (internal quotations and citations omitted). Lupin does not and cannot point to any abuse of discretion by this Court because there was none. Indeed, Lupin does not even attempt to argue that the Court abused its discretion in issuing the

Order. Instead, Lupin simply repeats its old arguments and claims the Court's disagreement with those arguments is reversible error. But Lupin never argues, let alone shows, that the Court of Appeals is likely to find an abuse of discretion by this Court. That Lupin disagrees with the Court's decision is understandable. But the Court's disagreement with, and rejection of, Lupin's positions most assuredly did not constitute an abuse of discretion. *See Nickson Industries, Inc. v. Rol Mfg. Co.*, 847 F.2d 795, 798 (Fed. Cir. 1988) ("Nickson's argument . . . is not based on evidence but merely reflects disagreement with the district court's approach. Such disagreement does not establish an abuse of discretion."); *see also Sullivan v. Db Invs.*, 2011 U.S. App. LEXIS 25185, at \*147-49 (3d Cir. Dec. 20, 2011) (refusing to find abuse of discretion where objectors merely "disagree[d] with the Court's factual findings" and "simply dislike[d] the conclusion reached by the Court").

Lupin's motion should be denied.

### III. ARGUMENT

Although styled as a Rule 62 motion to stay, and purportedly designed to "preserve the status quo," in reality, Lupin seeks reconsideration and vacatur of the Court's Order.<sup>1</sup> But, Lupin

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<sup>1</sup> Lupin claims the relevant status quo is the point in time *after* its at-risk launch, but *before* the grant of injunction. However, it is clear that the true status quo is the state of affairs *before* Lupin's infringing sales. *See Dominion Video Satellite, Inc. v. Echostar Satellite Corp.*, 269 F.3d 1149, 1155 (10th Cir. 2001) (affirming grant of preliminary injunction and finding that the status quo is "the last *uncontested* status between the parties which *preceded the controversy*."") (emphasis added).

The cases Lupin cites to support its "status quo" argument are unavailing. In *Standard Havens* and *DuPont* the equities were inverted. In *Standard Havens*, the non-movant's harm was "speculative and in any event cannot threaten its viability. On the other hand . . . [movant] Gencor's reasonably expected harm would be both catastrophic and irreparable." *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 516 (Fed. Cir. 1990). In fact, movant Gencor was in bankruptcy. *Id.* Similarly, in *DuPont* the non-movant had licensed all its competitors and was not actively enforcing its patent rights. *E.I. DuPont De Nemours & Co. v. Phillips Petroleum Co.*, 835 F.2d 277, 278 (Fed. Cir. 1987). Here, the Court has determined the opposite—that non-movant Shionogi, which is actively defending its patents, faces debilitating harm, while Lupin

(Continued . . .)

fails to identify any new facts, intervening law, or argument that the Court overlooked (because there are none). Thus, Lupin simply cannot justify its request that the Court vacate its Order and allow Lupin to engage in infringing conduct that the Court has already concluded would cause Shionogi “irreparable harm as defined by the Federal Circuit if Lupin’s launch is not enjoined.” (D.I. 279 at 18.) Instead, Lupin merely repeats the same arguments it already made during the preliminary injunction proceedings, in some instances apparently copying-and-pasting sections of its prior brief.

**A. Lupin Cannot Satisfy its Heavy Burden of Persuasion to Obtain a Stay under Rule 62**

**1. Legal Standard under Rule 62**

Lupin’s motion does not meet the heavy burden of Rule 62. To obtain a stay under Rule 62(c), Lupin must make a “strong showing” that (1) it is likely to succeed on the merits; (2) it will be irreparably injured absent a stay; (3) issuance of the stay will not substantially injure other interested parties; and (4) the public interest favors a stay. *Republic of Philippines v. Westinghouse Elec. Corp.*, 949 F.2d 653, 658 (3d Cir. 1991); *see also E. I. Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 659 F. Supp. 92, 96 (D. Del. 1987) (denying motion to stay permanent injunction pending appeal) (“When all is said and done, to stay the injunction

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(. . . continued)

does not. *See Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 397 F. Supp. 2d 537, 550 n. 69 (D. Del. 2005) (denying motion to stay because movant did not show a “need for judicial protection”).

Finally, in *Kawecki*, D.I. 289 at 5, the court only stayed that portion of the injunction which required a “positive act” by the enjoined party. *Kawecki Berylco Indus., Inc. v. Fansteel*, 517 F. Supp. 539, 542 (E.D. Pa. 1981) (“To stay *that portion of the Court’s order directing a positive act* by the defendant will preserve the status quo.”) (emphasis added). On the contrary, the Court’s injunction here only prevents Lupin from selling additional infringing product.



pending appeal and thus permit the massive past infringement to continue would eviscerate the public policy underlying the patent laws.”). In other words, the burden that Lupin now faces is far higher than the burden it faced in opposing Shionogi’s original motion for a preliminary injunction—and it cites no new facts or law to justify its request. Lupin cannot and does not meet its burden on any of these factors. Because each of these factors weighs heavily against granting Lupin’s motion, it should be denied.

Relief under Rule 62(c) is “anomalous” and Lupin bears a “very heavy burden of persuasion.” *Sanofi-Aventis*, 2009 U.S. Dist. LEXIS 56453, at \*6-7. Lupin’s burden is particularly high here because the considerations underlying a motion to stay essentially mirror those underlying the grant of preliminary injunction. *See Rennie v. Klein*, 481 F. Supp. 552, 554 (D.N.J. 1979) (“In view of the similarity of the standards governing decisions to issue preliminary injunctions and to stay their enforcement pending appeal, the defendants’ motion to stay pending appeal seems to be defective in certain crucial respects.”). Lupin may not, as it has done here, merely rehash the arguments it presented at the preliminary injunction phase to get a second bite at the apple. *See Tristrata Tech., Inc. v. ICN Pharms., Inc.*, 2004 U.S. Dist. LEXIS 6557, at \*10 (D. Del. 2004) (denying motion to stay injunction where movant’s positions were “merely repetitions of arguments previously rejected by the Court”); *E. I. DuPont*, 659 F. Supp. at 94 (“All of [the movant’s] arguments are warmed-over versions of its prior contentions upon which it did not prevail . . .”).<sup>2</sup>

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<sup>2</sup> Nor does simply restating old arguments justify reconsideration. *See Niblack v. Albino*, 2010 U.S. Dist. LEXIS 28447, at \*7 (D.N.J. 2010) (Kugler, J.) (“The standard for reargument is high and reconsideration is to be granted only sparingly. . . . The Court will grant a motion for reconsideration only where its prior decision has overlooked a factual or legal issue that may alter the disposition of the matter. The word ‘overlooked’ is the operative term in the Rule.”) (internal citations and quotations omitted).

Finally, Lupin's suggestion that it is likely to succeed on appeal must be analyzed in view of the standard of review—a standard Lupin completely ignores. The Federal Circuit reviews a “district court's decision to grant a motion for preliminary injunction for an abuse of discretion.” *Abbott Labs.*, 473 F.3d at 1200. The Federal Circuit will overturn the grant of a preliminary injunction *only* if the “district court made a clear error of judgment in weighing the relevant factors or based its exercise of discretion on an error of law or on clearly erroneous factual findings.” *Id.* (internal quotations and citations omitted).

Therefore, to prevail on its Rule 62 motion, Lupin must offer evidence to the Court beyond that already presented, and identify an abuse of discretion. Lupin has failed to do so and its motion should be denied.

## **2. Lupin Fails to Make the Required “Strong Showing” that it is Likely to Succeed on the Merits**

To prevail on its motion, Lupin must make a “strong showing” that it is likely to succeed on the merits, either at trial or on appeal. Lupin's motion focuses primarily on its alleged ability to succeed on appeal. However, Lupin is not likely to succeed on appeal because it cannot demonstrate that this Court abused its discretion in granting the preliminary injunction. *See Abbott Labs.*, 473 F.3d at 1200. Indeed, Lupin cannot even bring itself to argue that the Court abused its discretion, although it characterizes the Court's disagreement with Lupin's non-infringement and invalidity positions as legal error. But mere disagreement with, and rejection of, one party's position does not rise to the level of abuse of discretion. *See Nickson*, 847 F.2d at 798. Lupin's arguments that the Court applied improper legal standards or failed to address each and every argument in detail similarly lack merit. For these reasons, Lupin does not and cannot point to a legitimate abuse of discretion by the Court.

**a. The Court Did Not Abuse its Discretion in  
Rejecting Lupin’s Invalidity Arguments**

Lupin argues that the Court committed legal error by applying the wrong standard when evaluating the viability of Lupin’s invalidity arguments. The Court, however, applied the same standard Lupin now advocates in its motion; namely, that an alleged infringer need only raise a substantial question regarding invalidity. (D.I. 279 at 5-6; D.I. 289 at 5.). In its Opinion, the Court cited *Amazon.com v. Barnesandnoble.com*, 239 F.3d 1343, 1350 (Fed. Cir. 2001), for the proposition that, if Lupin “raises a substantial question concerning either infringement or invalidity . . . the preliminary injunction should not issue.” (D.I. 279 at 5-6.) The Court applied this standard and determined that it could not “resolve the question of validity in Defendant’s favor at this preliminary stage.” (*Id.* at 12.)

The Court’s reliance on *Amazon.com*—a case that Lupin itself relies upon in support of its motion (D.I. 289 at 10)—also disproves Lupin’s assertion that the Court required it to prove invalidity by clear and convincing evidence. (*See id.* at 5.) In *Amazon.com*, the Federal Circuit stated:

In resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself.

239 F.3d at 1359. As a result, it is apparent that the Court was aware of and considered a burden of proof requiring less than the clear and convincing evidence necessary to prove invalidity at trial when determining that Lupin had not shown “vulnerability” and Shionogi would likely succeed on the merits.

The Court’s citation to *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238, 2242 (2011), and *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1574-75 (Fed.

Cir. 1984), does not suggest otherwise. In its Opinion the Court properly found that, in view of the presumption of validity that applies to Shionogi's patent, and Lupin's heavy burden of proving invalidity by clear and convincing evidence at trial, Lupin had failed to raise a substantial question of invalidity at this preliminary stage. In doing so, the Court did not commit reversible error, but instead made a determination consistent with longstanding Federal Circuit and Supreme Court precedent. *See Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 429 (2006) (“[T]he burdens at the preliminary injunction stage track the burdens at trial.”); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1056 (Fed. Cir. 2010) (in granting preliminary injunction, district court did not “clearly err by concluding that at trial [defendant] will likely not be able to demonstrate the clear and convincing evidence that the [prior art] anticipates the asserted method claims”). *See also Abbott Labs.*, 473 F.3d at 1201 (“[In order to defeat the injunction based on invalidity or unenforceability defenses, [defendant], as the party bearing the burden of proof on the issue at trial, must establish a substantial question of invalidity or unenforceability, i.e., that it is likely to succeed in proving invalidity or unenforceability of the asserted patents.”). There was no clear error in the Court's finding that Lupin had not raised a substantial question of invalidity.

**b. Lupin's Motion Repeats the Same Invalidity Arguments Considered and Rejected by the Court**

Despite extensive briefing and argument regarding the prosecution history of the '866 patent, Lupin simply retreads old ground by once again arguing that claim 1 of the '866 patent is not entitled to a presumption of validity. Claiming, as it did at oral argument, that claim 1 issued because of a “printer's mistake,” Lupin brings no new facts, argument, or legal issues to the

Court.<sup>3</sup> Lupin simply reargues the same position it took during the preliminary injunction proceedings. Having heard these *exact* arguments before and concluding that “claim 1, as it appears in the ‘866 patent, was indeed approved by the PTO,” (D.I. 279 at 12.) the Court should deny Lupin’s motion.<sup>4</sup> *See Tristrata Tech.*, 2004 U.S. Dist. LEXIS 6557 at \*10 (denying motion to stay injunction where movant’s positions were “merely repetitions of arguments previously rejected by the Court”).

**c. The Court Did Not Fail to Address Lupin’s Invalidity Arguments**

Lupin also claims that the Court “neglect[ed] to address the substance of defendants’ argument that the patent is invalid for obviousness.” (D.I. 289 at 7). Lupin’s obviousness argument—fully briefed and argued to the Court during the preliminary injunction proceedings—was not “overlooked.” To the contrary, the Court expressly recognized that Lupin was “arguing that claim 1’s  $T_{\max}$  of 5.5. to 7.5 hours had been rejected as obvious.” (D.I. 279 at 11.) Just because the Court did not accept Lupin’s argument does not mean it was ignored.

The Court also rejected Lupin’s assertion that the ‘866 patent was not entitled to a presumption of validity, and in doing so, concluded “Shionogi is likely to succeed in its claim that its patent is valid because of the strong presumption favoring the validity of existing

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<sup>3</sup> Moving beyond Lupin’s selective reading of the prosecution history and its concerns about “the erroneously printed patent claims” (D.I. 289 at 7), Lupin recognizes, as it must, that the patent examiner “approved claims with a  $T_{\max}$  ceiling of ‘7 hours,’” *i.e.*, claim 3 – a claim also asserted against Lupin by Shionogi in this litigation. (*See id.* at 6.)

<sup>4</sup> Once again, Lupin maintains that the examiner had concluded that claim 1 was obvious some time after the Notice of Allowance issued. (D.I. 289 at 7.) However, Lupin and its expert have already admitted that *all* of the claims, including claim 1, of the ‘866 patent were allowed and issued. (Steiner Dec. ¶ 33; *see also* D.I. 289 at 7.) Thus, regardless of whether Lupin believes that “the claims that issued in the ‘866 patent were the wrong claims” (*Id.* at 6), it has failed to demonstrate, much less make a strong showing, that all the asserted claims, including claim 3, are not entitled to the presumption of validity.

patents.” (*Id.* at 11.) This conclusion necessarily addresses and rejects Lupin’s argument that its prior art—nearly all of which the Patent Office considered previously—rendered the ‘866 patent obvious. To the extent Lupin’s complaint is about the detail with which the Court addressed Lupin’s prior art references in the Opinion, that is not a basis for reversal on appeal and, as a result, cannot support Lupin’s Rule 62 motion. *See, e.g., Xytec Plastics, Inc. v. Ropak Corp.*, 1992 U.S. App. LEXIS 260, at \*6-11 (Fed. Cir. Jan. 8, 1992) (internal citations omitted) (affirming grant of preliminary injunction and stating “[t]he only error with respect to this issue that appellant argues is the lower court’s failure to discuss the prosecution history and prior art explicitly. . . . [However], the appellant has ignored our oft-repeated position that ‘we sit to review judgments, not opinions.’ . . . We review judgments and orders, not the particular language with which the trial court chose to express itself. . . . [Defendant] fails to show that the court actually failed to examine the prior art.”).

**d. The Court Did Not Abuse its Discretion in Rejecting Lupin’s Non-Infringement Arguments**

Lupin’s motion also reargues the same non-infringement positions that the Court rejected. And, once again, Lupin fails to offer the Court any new or different facts, law, or arguments that would justify its requested relief under Rule 62 or otherwise. *See Tristrata Tech.*, 2004 U.S. Dist. LEXIS 6557 at \*7; *DuPont*, 659 F. Supp. at 94. In particular, Lupin attempts to disavow its FDA-approved label yet again, despite the Court’s extensive discussion of Lupin’s label and its conclusion that “the ANDA specifications of Defendant’s product control this Court’s infringement inquiry.” (D.I. 279 at 10.) Lupin’s disagreement with this determination, as well as the applicability of *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367 (Fed. Cir. 2002), does not demonstrate reversible error and is not a basis to grant a Rule 62 motion.

In addition, Lupin criticizes the Court for “refusing to consider the test results” of the fundamentally flawed study that Lupin props up as evidence on non-infringement, but admittedly never submitted to the FDA. Lupin’s criticism lacks merit. The Court did address Lupin’s study and observed that it “offers evidence that Defendant’s product may not infringe.” However the Court ultimately concluded that this evidence fails to “raise[] a substantial question” of non-infringement when crediting expert testimony that the study was flawed. (D.I. 279 at 9.) There is no legal error or abuse of discretion in this analysis.

Finally, Lupin restates an alleged non-infringement position by proposing a construction of the claim term “single dose” that is contrary to the definition that Lupin itself asserted during claim construction proceedings. During claim construction, Lupin agreed with Shionogi and argued that “single dose” means “the amount of the drug administered to a human patient at one time.” (See D.I. 159 (Lupin’s Claim Construction Opening Brief) at 15.) The Court accepted that construction without qualification. (D.I. 192.) Now, as it did in its preliminary injunction papers, Lupin attempts to avoid infringement by instead interpreting “single dose” to mean the amount of drug administered at one time ever, such that the drug cannot achieve a “steady state.”<sup>5</sup> (Cf. D.I. 289 at 8 and D.I. 230 at 18.) The Court did not commit error when it rejected this argument in granting Shionogi’s preliminary injunction. See *Mytee Prods. v. Harris Research, Inc.*, 2011 U.S. App. LEXIS 18465, at \*8 (Fed. Cir. 2011) (precluding argument based on new claim construction because “Mytee’s argument, if accepted, would enable it to

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<sup>5</sup> This litigation-induced argument appeared nowhere in this case prior to Lupin’s briefing on the preliminary injunction motion, in contravention of N.J. Local Patent Rule 3.6, and should be deemed waived. See *Fenner Inv., Ltd. v. Microsoft Corp.*, 632 F. Supp. 2d 627, 638 (E.D. Tex. 2009) (“Because this argument is contrary to the claim construction order and was not raised prior to or even following the claim construction hearing it is waived.”).

circumvent a limitation that Mytee itself proposed during claim construction.”); *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 715 (Fed. Cir. 1998) (refusing to revise a construction that the alleged infringer itself “urged upon the trial court as correct.”)

**B. Lupin Will Not Be Irreparably Harmed Without Stay of the Injunction**

Lupin contends that without a stay it will suffer “irreparable harm” as a result of the Court’s “wrongfully-granted preliminary injunction.” (D.I. 289 at 1.) This is incorrect for three reasons. First, as the Court recognized, Lupin decided to launch its generic copy of FORTAMET® “at-risk,” and with full knowledge that it could be enjoined from shipping additional product. (*See* D.I. 279 at 19.) In doing so, Lupin made the fully-informed choice to start the clock running on its 180-day exclusivity, despite the well-known risk of an injunction. Lupin’s complaint that it is being harmed by the injunction despite this reasonably foreseeable risk strains credulity and was properly rejected by this Court.

Second, once again, Lupin essentially repeats the same arguments this Court has already rejected. (*Compare* D.I. 289 at 13-15 (Arguing that Lupin will suffer harm from overall decline of the FORTAMET® market, lose its 180-day exclusivity period, and lose its one-year advantage) *with* D.I. 230 at 32-34 (same).) Lupin’s insinuation that the Court must not have considered those arguments because the Court did not agree with them is unfounded. (D.I. 289 at 12.)

Third, the additional harms Lupin alleges in its motion do not withstand scrutiny. Lupin cites the recent drop in its stock price, which it believes was “in reaction to the news of the preliminary injunction order.” (*Id.* at 12 n.4, Ex. B.) But Lupin fails to mention that the exchange on which its stock is listed, the National Stock Exchange of India, witnessed an overall decline of about 6% between December 5 and December 12, 2011 (the Exchange was closed on



December 6, the date of the injunction order), which is not significantly different from the fall in the price of Lupin's stock of about 6.5%. *See, e.g.,* Yahoo! Finance, <http://finance.yahoo.com/q/bc?s=%5ENSEI&t= 3m&l= on&z= 1&q= 1&c=lupin.ns>. The vagaries of the Indian stock market hardly suffice to prove irreparable harm.

Lupin also worries that it will “lose potential market share . . . if Watson is permitted to sell its product.” (D.I. 289 at 13.) This wholly speculative risk, entirely of Lupin's own making, is belied by Lupin's own recent argument to this Court that loss of market share is insufficient to show irreparable injury. (D.I. 230 at 25 (“If loss of market share were sufficient to show irreparable injury, then every generic product would be enjoined at the request of the brand manufacturer.”); *id.* at 27 (“loss of market share . . . is compensable with money damages”).)

### **C. The Balance of Hardships Has Not Shifted**

Incredibly, Lupin argues that the balance of hardships now favors Lupin. The Court has already considered the same harms claimed by Lupin during the preliminary injunction proceedings, weighing Lupin's alleged harm against the greater harm that Shionogi has faced (and will face) without an injunction. The Court properly determined that the balance of hardships favors Shionogi. (D.I. 279 at 19). Lupin's motion does not provide any new facts or arguments demonstrating that this balance has shifted.

Lupin also repeats its (previously rejected) argument that “Shionogi will suffer the same irreparable injuries” regardless of whether Lupin is enjoined because Lupin believes that Watson “most likely will” enter the market even in Lupin's absence. (D.I. 289 at 12-13.) But this unsupported belief is even more speculative now than it was when Lupin first raised it. (*See, e.g.,* D.I. 230 at 28 (“[A]ll of the harm which Shionogi claims has befallen it . . . will continue even if Lupin is enjoined, because [Watson's] authorized generic will create the same

problems.”)) More than two weeks have passed since the Court ordered the injunction, and Watson has not entered the market.

In addition, Lupin repeats its suggestion, first made at the December 2 hearing, that the recent increase in the price of FORTAMET® shows that Shionogi will not face price erosion if it has to compete with Lupin. (D.I. 289 at 17.) However, Shionogi’s expert, Dr. Vellturo, has already opined that any increase in price may be more than offset by discounts and rebates Shionogi will need to make in order to maintain or restore its formulary status. (Vellturo Decl. ¶¶ 49-53.) This point also was argued and addressed at the preliminary injunction hearing.

Finally, Lupin argues that a stay is appropriate where “harm to third parties seems minimal,” or where “the non-moving party would not be substantially harmed by the [] stay.” (D.I. 289 at 4-5.) But this Court already determined that Shionogi *would* be irreparably harmed, suffering “loss of market share, price erosion, and loss of goodwill,” unless Lupin is enjoined. (D.I. 279 at 13; *see id.* at 18.) As a result, Lupin’s suggestion that harm to Shionogi would be minimal, particularly when Lupin’s requested stay would cause the very harm the injunction is designed to avoid, lacks merit.

#### **D. The Public Interest Favors Maintaining the Injunction**

Lupin argues that “irregularities in the PTO” regarding the asserted patent somehow outweigh the public interest in protecting patent rights. (D.I. 289 at 20.) However, as already recognized by the Court, “[t]he presumption of [a patent’s validity] is never annihilated, destroyed, or even weakened, regardless of what facts are of record.” (D.I. 279 at 12.) Accordingly, the public interest in strong patent rights is favored, and at least balances the interest in the availability of generic drugs.

**E. There is No Basis to Modify the Order for Preliminary Injunction**

In the alternative, Lupin requests that the Court modify the Order “to provide that it will be stayed immediately and without further action needed by any party if another generic FORTAMET® product enters the market.” (D.I. 289 at 20.) As demonstrated above, Lupin’s motion to stay provides no basis for the Court to revisit and modify its Order. The sole basis for Lupin’s request to modify—the potential for Watson’s entry into the market as an Authorized Generic—was extensively briefed and argued to the Court and existed at the time the Court entered the injunction. Lupin’s motion changes nothing and provides no new or additional reasons for the Court to evaluate.

**IV. CONCLUSION**

For the reasons set forth above, the Court should deny Lupin’s motion to stay the Order for Preliminary Injunction.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Karen Jacobs Loudon*

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Jack B. Blumenfeld (#1014)  
Karen Jacobs Loudon (#2881)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899-1347  
(302) 658-9200  
jblumenfeld@mnat.com  
klouden@mnat.com

*Attorneys for Plaintiff Shionogi, Inc.*

**OF COUNSEL:**

David A. Manspeizer  
David B. Bassett  
Peter Shen  
Christopher Noyes  
WILMER CUTLER PICKERING HALE AND DORR  
LLP  
399 Park Avenue  
New York, NY 10022  
(212) 230-8800

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**CERTIFICATE OF SERVICE**

I hereby certify that on December 23, 2011, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following all registered participants.

I also certify that copies were caused to be served on December 23, 2011 upon the following in the manner indicated:

Richard D. Kirk, Esquire  
Stephen B. Brauerman, Esquire  
BAYARD, P.A.  
222 Delaware Avenue, Suite 900  
Wilmington, DE 19801  
*Attorneys for Lupin Ltd. and Lupin  
Pharmaceuticals, Inc.*

*VIA ELECTRONIC MAIL*

Douglass C. Hochstetler, Esquire  
KELLEY DRYE & WARREN LLP  
333 West Wacker Drive, 26<sup>th</sup> Floor  
Chicago, IL 60606  
*Attorneys for Lupin Ltd. and Lupin  
Pharmaceuticals, Inc.*

*VIA ELECTRONIC MAIL*

Beth D. Jacob, Esquire  
KELLEY DRYE & WARREN LLP  
101 Park Avenue  
New York, NY 10178  
*Attorneys for Lupin Ltd. and Lupin  
Pharmaceuticals, Inc.*

*VIA ELECTRONIC MAIL*

Karen A. Confoy, Esquire  
Erica A. Helms, Esquire  
STERN & WEINROTH PC  
50 West State Street, Suite 1400  
Trenton, NJ 08607  
*Attorneys for Lupin Ltd. and Lupin  
Pharmaceuticals, Inc.*

*VIA ELECTRONIC MAIL*

Richard Herrmann, Esquire  
Mary B. Matterer, Esquire  
MORRIS JAMES LLP  
500 Delaware Avenue, Suite 1500  
Wilmington, DE 19801  
*Attorneys for Mylan Inc. and Mylan  
Pharmaceuticals Inc.*

*VIA ELECTRONIC MAIL*

Timothy H. Kratz, Esquire  
Robert L. Florence, Esquire  
George J. Barry III, Esquire  
MCGUIRE WOODS LLP  
1230 Peachtree Street, N.E., Suite 2100  
Atlanta, GA 30309  
*Attorneys for Mylan Inc. and Mylan  
Pharmaceuticals Inc.*

*VIA ELECTRONIC MAIL*

Frederick L. Cottrell, III, Esquire  
Steven J. Fineman, Esquire  
RICHARDS, LAYTON & FINGER P.A.  
One Rodney Square  
Wilmington, DE 19801  
*Attorneys for Andrx Corporation, Andrx  
Pharmaceuticals, Inc. (n/k/a Watson  
Laboratories, Inc.-florida), Andrx  
Pharmaceuticals, L.L.C., Andrx Laboratories  
(NJ), Inc., Andrx EU Ltd. and Andrx Labs,  
L.L.C.*

*VIA ELECTRONIC MAIL*

Gary E. Hood, Esquire  
POL SINELLI SHUGHART PC  
161 North Clark Street, Suite 4200  
Chicago, IL 60601-3316  
*Attorneys for Andrx Corporation, Andrx  
Pharmaceuticals, Inc. (n/k/a Watson  
Laboratories, Inc.-florida), Andrx  
Pharmaceuticals, L.L.C., Andrx Laboratories  
(NJ), Inc., Andrx EU Ltd. and Andrx Labs,  
L.L.C.*

*VIA ELECTRONIC MAIL*

Robyn H. Ast, Esquire  
POL SINELLI SHUGHART PC  
100 South Fourth Street, Suite 1000  
St. Louis, MO 63102  
*Attorneys for Andrx Corporation, Andrx  
Pharmaceuticals, Inc. (n/k/a Watson  
Laboratories, Inc.-florida), Andrx  
Pharmaceuticals, L.L.C., Andrx Laboratories  
(NJ), Inc., Andrx EU Ltd. and Andrx Labs,  
L.L.C.*

*VIA ELECTRONIC MAIL*

*/s/ Karen Jacobs Louden*

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Karen Jacobs Louden (#2881)